DETAILED ACTION

The response and amendment filed 4-18-08 has been entered into the record. Claims 1-11 have been cancelled and claims 12-13 are pending.

Priority

Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

Information Disclosure Statement

The information disclosure statement filed 2-22-06 has been considered. An initialed copy is enclosed.

Election/Restrictions

Applicant's election of Group II, specie Salmonella in the response filed 4-18-08 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 12 and 13 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial and credible or well established asserted utility or a well established utility.

The claims are drawn to a method of protecting a susceptible human or animal from infection with a pathogenic bacterium comprising administering an effective amount of a vaccine comprising a live attenuated bacterium of the genus *Salmonella*, wherein the bacterium does not have a functional $tRNA_5^{leu}$ and a pharmaceutically acceptable carrier.

The art does not recognize protection from infection using vaccines. Protection from infection is equivalent to prevention of infection. Protection/prevention of infection means that a single organism does not enter into tissues or cells of a subject's body. Prophylactic treatments e.g. vaccines for many infections kill the organism once it infects tissues or cells thus preventing disease due to said infections but such treatments do not protect/prevent the organism from infecting in the first place. The human/animal body is naturally "infected" with many intracellular organisms how does one protect/prevent these infections? Protection/prevention of infection by all pathogenic organisms in general is a very high bar for which the art does not recognize as possible or probable. Also, protection/prevention of infection is different from protection/prevention of disease caused by an infection as protection/prevention of disease is prevention of symptoms due to an infection while protecting/preventing infection is inhibition of the infectious organism from invading or entering, for example, the human body, tissue, cells in the first place. Protection/prevention of all infections caused by all pathogenic bacteria by a single vaccine comprising a attenuated *Salmonella* as claimed is inconsistent with the plethora of teachings of the vaccine art indicating that protection from disease by heterologous organisms (i.e. immunization with *E. coli* protects from disease with *S. typhi* or immunization with *S. typhi* protects from disease with *S. typhimurium*) is vanishingly rare. The teaching of the art is replete that vaccine immunization protects against or treats disease against only the *homologous organism* and not other species within the genus and certainly not other Genera within the Family. There is no attenuated bacterium in the art that treats or protects from disease from all pathogenic organisms. In summary, it would

be reasonable to conclude that the utility of the instant claims would is not credible and is not well established based on the evidence of record.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12 and 13 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial, and credible or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claims 12 and 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.
The claims are drawn to use of a vaccine wherein the microrganims of the genus of Salmonella lacks a functional tRNA5leu. It is noted that this gene is called leuX and is described in the art for *E.coli*. The *S. typhimurium* equivalent is described herein as SEQ ID NO:1. The claims encompss three genera, Escherichia, Salmonella and Yersinia. In order to make non-functional mutants of leuX (tRNA5leu), the skilled artisan must be in

possession of the target sequence. In the instant case the target sequence for *E. coli* was described in the art and the target sequence for *S. typhimurium* was described in the specification. No target sequence is described for any *Yersinia* spp (see Entrez, cross database search for LeuX genes). Furthermore, the description of a single leuX gene sequence for *Salmonella typhimurium* does not put applicant in possession of the of leuX genes for the claimed Genera (*Salmonella, Escherichia and Yersinia*) at the time of invention as of the priority date in 2003. Possession of a genus may not be shown by merely describing how to obtain members of the claimed genus or how to identify their common structural features. See *University of Rochester*, 358 F.3d at 927, 69 USPQ2d at 1895.

Status of the Claims

Claims 12 and 13 stand rejected.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can normally be reached on M-Th 6:30 am - 6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor Shanon Foley can be reached on 571-272-0898.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Patricia A. Duffy/

Patricia A. Duffy, Ph.D.

Primary Examiner

Art Unit 1645